G. Craig Llewellyn, Ph.D.
Principal and Scientific Director
Toxicology Regulatory Services (TRS), Inc.
SafeBridge Regulatory and Life Sciences Group
A Trinity Consultants Inc. Company
154 Hansen Road, Suite 201
Charlottesville, VA 22911

Re: GRAS Notice No. GRN 000998

Dear Dr. Llewellyn:

The Food and Drug Administration (FDA, we) is granting the request on behalf of AgriFiber Solutions, LLC (AgriFiber) to cease our evaluation of GRN 000998, which we filed on July 6, 2021. We received this request on September 10, 2021.

The subject of the notice is corn bran arabinoxylan for use as a formulation aid at a maximum use level of 3% (e.g., binder, gelling agent, texturizer, stabilizer, thickener, and/or emulsifier), and as a source of dietary fiber at a maximum use level of 3.8 g/serving in a variety of food categories and at a maximum use level of 7.6 g/serving in yogurt, smoothies and grain drinks, and powdered nutritional supplements.[1] The notice informs us of AgriFiber's view that these uses of corn bran arabinoxylan are GRAS through scientific procedures.

In a September 10, 2021 meeting, we informed you that we identified multiple issues during our evaluation of Part 6, the Narrative, of GRN 000998. In addition, we stated the notice did not elucidate the similarities and differences between substances used as test articles in published safety studies and the subject of GRN 000998. We also asked that you provide information on the use levels for some of the intended food categories. Given the scope of the issues identified, we recommended that you request we cease our evaluation of the notice. We also suggested that you request a pre-submission meeting with us to discuss how you propose to address our questions in a future submission. In an email dated September 10, 2021, you requested on behalf of AgriFiber that we cease our evaluation of GRN 000998.

[1] The notice excluded uses in meat and poultry products under the jurisdiction of the United States Department of Agriculture, and infant formula.

In accordance with 21 CFR 170.275(b)(3), the text of this letter responding to GRN 000998 is accessible to the public at www.fda.gov/grasnoticeinventory.

Sincerely,

Susan J. Carlson -S

Digitally signed by Susan J. Carlson -S
Date: 2021.10.25 09:55:52 -04'00'

Susan Carlson, Ph.D.
Director
Division of Food Ingredients
Office of Food Additive Safety
Center for Food Safety
and Applied Nutrition